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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/527,442	03/17/2000	Thomas P. Jerussi	4821-369-999	3088
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20582 7590 07/02/2002

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EXAMINER

BARTS, SAMUEL A

ART UNIT

PAPER NUMBER

1621

DATE MAILED: 07/02/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/527,442

Applicant(s)

JERUSSI ET AL.

Examiner

Samuel A Barts

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 and 30-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-29 and 52-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of claims 27-29 and 52-59, which are directed to methods of reacting affective disorders, in Paper No. 14 is acknowledged. The traversal is on the ground(s) that "the examination of all claims in Group V would not impose an unreasonable burden on the Examiner." This is not found persuasive because the diverse disorders being treated are not recognized as being obvious over one another. For example, a reference directed to the treatment of depression would not render obvious the claims drawn to the treatment of epilepsy, obesity, and pain, Parkinson etc. The examiner would thus be required to search for each additional disorder. This additional searching would be a serious undue burden to the examiner. If applicant admits on the record that the disorders are obvious, the claims will be examined together.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 27-29 and 52-59 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Taft et al

("Application of a First-Pass Effect Model to Characterize the Pharmacokinetic Disposition of Venlafaxine after Oral Administration to Human Subjects "; DRUG METABOLISM AND DISPOSITION, Vol. 25, No. 10, pages 1215-1218, October 1997.).

Applicant's claims are drawn to the treatment of affective disorders by the administration of O-desmethylvenlafaxine (ODV) to a human subject. Affective disorders include depression (see claim 29). Taft et al teaches the treatment of depression by the administration of "oral" doses of venlafaxine. ODV is a major metabolite of venlafaxine. See column 1 page 1215 second paragraph. ODV has antidepressant activity. Thus, there is no distinction in administering ODV directly or through the parent drug venlafaxine since, in both cases ODV is treating depression.

The dependent claims are drawn to minor requirements such as amounts given, the recitation of the +/- enantiomers (both of which are inherent in the racemic mixture) and using the HCl salt of ODV. These variables all appear to

be encompassed by the disclosure of Taft et al. For example, Taft teaches administering the drug in an amount base on body weight of 1.5 mg/kg. A person weighing 200 lbs would translate to about 132mg. Taft et al teaches the use of HCL when making the venlafaxine composition.

If Taft et al do not encompass theses limitations they are obvious since they are so routine in nature. One of ordinary skill in the art would have been motivated to adjust the amounts, solvents, carriers etc in order to prepare the composition of venlafaxine for administering to different subjects. Criteria such as age, weight, severity of depression being treated etc would all lead a skill artisan to tweak the mode of administration.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel A Barts whose telephone number is 703-308-4630. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johan Richter can be reached on 308-1235. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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Samuel A Barts  
Primary Examiner  
Art Unit 1621

s.b.  
June 30, 2002